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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,946	08/08/2001	Mark J. Evans	0630/1G703US2	3104

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EXAMINER

PAK, YONG D

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 04/08/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/924,946

Applicant(s)

EVANS ET AL.

Examiner

Yong Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 16 and 21-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-15 and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 7 & 8. 6) ☐ Other: _____

DETAILED ACTION

The amendment filed January 13, 2003, amending claims 8 and 30, has been entered.

Claims 1-46 are pending.

Election/Restrictions

Applicant's election with traverse of Group II (claims 8-15 and 17-20) in Paper No. 10 is acknowledged. The traversal is on the ground(s) that Groups V and VII should be examiner with Group II. This is not found persuasive because Group II and Groups V and VII are related as product and process of use. The inventions are distinct because the product of Group II can be used in a materially different process of using that product (MPEP § 806.05(h)), such as in a method of producing a polypeptide. Also, because of the recognized divergent subject matter, an unduly extensive and burdensome search is required for Groups V and VII that is not required for Group II.

Claims 1-7, 16 and 21-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-10, 13-15 and 17-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 8-10, 13-15 and 17-20 are drawn to DNA that is at least 60% identical to SEQ ID NO:2 or DNA encoding polypeptide comprising at least 10 contiguous amino acids of SEQ ID NO:2. A description of roughly over half of the whole structure of SEQ ID NO:2 and only 10 amino acids, which represents about 1% of the whole structure of SEQ ID NO:2, amount to insufficient description of the structure of the DNA molecule in this claim. The genus of DNA that comprise these above fragments and portions of SEQ ID NO:2 is a large variable genus with the potentiality of encoding many different proteins. Therefore, these claims are drawn to a large variable genus of DNA molecules encoding polypeptides with an insufficient limitation on structure. The specification teaches DNA encoding the EER-7 of SEQ ID NO:2. The specification does not describe the function of all the polypeptide sequences encoded by the DNA molecules derived or

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modified from SEQ ID NO:2 and therefore, many functionally unrelated polypeptides are encompassed within the scope of these claims. Therefore, many structurally and functionally unrelated DNA are encompassed within the scope of these claims, including partial DNA sequences. The specification fails to describe any other representative species by any identifying characteristics or properties other than the "functionality" of encoding a EER-7 and fails to provide any structure: function correlation present in all members of the claimed genus.

Given this lack of the description of the representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 8-10, 13-15 and 17-20.

Claims 8-10, 13-15 and 17-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA encoding the EER-7 of SEQ ID NO:2, does not reasonably provide enablement for DNA molecules encoding EER-7 that is different from SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir., 1988). They include (1) the quantity of experimentation necessary, (2) the amount of

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direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims encompass molecules having very low structural similarity to SEQ ID NO:2 that exhibit EER-7 protein activity. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of constructs broadly encompassed by the claims. Also, despite knowledge in the art for the isolation of amino acids, the specification fails to provide guidance regarding how to isolate other EER-7 protein whose sequence is not homologous to SEQ ID NO:2. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen a large number of possible combinations .

The predictability as to the level of conservation between the disclosed sequences and those of other EER-7 is extremely complex. While recombinant techniques are available, it is not routine in the art to screen large numbers of amino acids where the expectation of obtaining similar sequences is unpredictable. The amino acid sequence determines the structural and functional properties of an enzyme. Knowledge of which sequences can be altered or removed and still result in similar protein activity is well outside the realm of routine experimentation.

Therefore, one of ordinary skill would require guidance in order to make DNA encoding a EER-7 protein different from SEQ ID NO:2 in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-15 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 8-15 and 17-20, the mere recitation of the name "EER-7" is insufficient to convey with clarity that which applicant sees as the invention. Also, the mere recitation of "SRCR" is insufficient to convey with clarity that which applicant sees as the invention.

In claims 18-20, the exact hybridization condition is unclear. Different nucleic acids hybridize to a DNA sequence under different conditions. Therefore, the scope of DNA molecules in claims 18-20 is unclear.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2-10, 13-15 and 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Meyers.

Meyers (U.S. Patent Application Publication No. US 2002/0068322) teach a DNA molecule encoding a lysyl oxidase that is 99.9% identical to SEQ ID NO:2, differing by only one residue at position 405 (pages 39-40, abstract). The lysyl oxidase of Meyers comprises of four scavenger receptor cysteine-rich (SRCR) domains that is greater than 80% similar to SQ ID NO:3, 4, 5 and 6 and the oxidase of Meyers also comprises of the conserved catalytic domain of lysyl oxidase enzymes as depicted in SEQ ID NO:7. Meyers also teaches vectors comprising said DNA, host cell transfected with said vector, a method of producing the protein and nucleic acid molecules of at least 20 bases that hybridizes under stringent conditions with SEQ ID NO:1, which are also labeled (pages 7-19). Therefore, the teachings of Meyers anticipate claims 8-10, 13-15 and 17-20.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

A handwritten signature in black ink, appearing to read 'Yong Pak', written in a cursive style.

April 3, 2003